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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/633,793	08/07/2000	Thor Halseth	1032-P01510US1	3022
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DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,793

Applicant(s)

HALSETH ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 7-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The inventions are distinct, each from the other because of the following reasons:

- I. Claims 1-6, drawn to method of use, classified in class 604, subclass 181.
- II. Claims 7-13, drawn to apparatus, classified in class 604, subclass 192-198.

The inventions are distinct, each from the other because of the following reasons”

1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case because Group I does not have all the limitations described in the apparatus of Group II, for example Group I lacks the plunger having a cavity for receiving a portion of the needle after retraction of the needle, or the multiple seals discussed in the limitations of Group II. Therefore there could be multiple methods of use for the apparatus for Group II and it is not limited to the method described in Group I.
2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
3. During a telephone conversation with Mr. Eland on 7-03-02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claims 7-13 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the skin" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "fluid" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the pH level" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,964,735 to Alexander.

Alexander discloses a fine needle aspiration safety syringe. Alexander's apparatus provides a sampling device with a housing and a retractable needle. Alexander's syringe is capable of collecting fluid from the patient and seal it in the housing as well as expelling the fluid from the housing with a plunger.

6. Claims 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,085,640 to Gibbs.

Gibbs discloses a non-reusable medical needle apparatus. Gibbs's apparatus provides a sampling device with a housing and a retractable needle. The fluid, which has been, collected from the patient may be sealed in the housing and then expelled from the housing after the needle has been retracted. (Figures 38-42)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5-6 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5085640 to Gibbs or U.S Patent No.5964735 to Alexander.

As mentioned above, both Gibbs and Alexander's apparatus provide a sampling device with a housing and a retractable needle. Furthermore, the fluid, which has been, collected from the patient may be sealed in the housing and then expelled from the housing after the needle has been retracted. Neither Gibbs nor Alexander discloses the analysis of the pH level of the collected fluid. However, it is common practice in medicine to analyze the collected fluid, for the most part with a few exceptions, the fluid is collected for the sole purpose of some type of analysis. The type of analysis done to the collected fluid (i.e. pH level) depends on the singe, the symptom, past medical history, current potential diagnosis, and family history of the patient. In case of analysis of pH level in bodily fluid, it is mostly indicated whenever a clinically important acid-base disturbance occurs, for example when hypoxemia or hypercapnia are suspected. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the fluid collected from the patient for some type of analysis (i.e. pH level) to help with the diagnostic or treatment process.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S Patent No.6001080 to Kuracina et al

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


RG
July 3, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700